K033997

FEB - 4 2004

510(k) Summary

General Information

Classification	Class II
Trade Name	Solera™ Plus Thrombectomy Catheter
Submitter	Bacchus Vascular, Inc. 3110 Coronado Drive Santa Clara, CA 95054 408-980-8300
Contact	Gregory J. Mathison Regulatory Affairs Consultant

Intended Use

The Solera Plus Thrombectomy Catheter permits mechanical thrombectomy of synthetic dialysis grafts.

Predicate Devices

Solera Thrombectomy Catheter Manufactured by Bacchus Vascular, Inc.	K003570
Solera MagnumThrombectomy Catheter Manufactured by Bacchus Vascular, Inc.	K022640

Device Description

The Solera Plus is a single-use, over-the-wire disposable catheter, with an integral Motor Drive Unit (MDU). The Solera Plus has a central hollow drive shaft connected to an expanding clot maceration and removal system. The clot removal system is comprised of a Nitinol macerator and a Nitinol outer protective basket. The macerator is attached to the drive shaft and rotates within the stationary protective basket. The protective basket expands to the lumen diameter and acts to protect the graft wall from the rotating macerator. Mechanical aspiration is achieved by rotation of the drive shaft and by an applied vacuum (locking syringe). The rotation of this drive shaft in conjunction with the vacuum causes material to be pumped out of the treatment area after maceration. Aspiration is controlled (i.e., on/off) by a button on the motor drive unit, which may be activated by the physician to allow flow out of the Solera Plus. The default position is 'off' to and is designed to minimize blood loss during the procedure.

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Materials

All materials used in the manufacture of the Solera Plus are suitable for this use and have been used in numerous previously cleared products.

Testing Summary

The Solera Plus Thrombectomy Catheter was tested in the same manner as the Solera Magnum Thrombectomy Catheter (K022640). All components, subassemblies, and/or full devices met the required specifications for the completed tests. The Solera Plus was designed under the Bacchus Quality System which is in compliance with 21CFR§820.30.

Summary of Substantial Equivalence

The Solera Plus Thrombectomy Catheter is equivalent to the predicate product, the Solera Magnum Thrombectomy Catheter. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent. Bacchus Vascular, Inc. believes the Solera Plus Thrombectomy Catheter is substantially equivalent to existing legally marketed devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2004

Bacchus Vascular, Inc
c/o Ms. Lisa Caparra
3110 Coronado Drive
Santa Clara, CA 95054

Re: K033997
Solcra Vascular Plus Thrombectomy Catheter
Regulation Number: 21 CFR 870.4875
Regulation Name: Catheter, Peripheral, Atherectomy
Regulatory Class: Class II
Product Code: MCW
Dated: January 27, 2004
Received: January 28, 2004

Dear Ms. Caparra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram Zuckerman, M. D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):	~~This application~~ -> K033997
Device Name:	Solera Plus Thrombectomy Catheter
Indications for Use:	The Solera Plus Thrombectomy Catheter permits mechanical thrombectomy of synthetic dialysis grafts.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

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